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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,599	10/29/2003	Austin L. Gurney	39766-0125A	7558

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HELLER EHRMAN LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,599	GURNEY, AUSTIN L.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16, 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. The Applicant's response to the office action mailed on 3/14/2006, including arguments/remarks and amendments to the claims and specification, was received on 8/9/2006 and has been entered into the record.

2. Claims 1-13, 17, and 29-49 were cancelled in the amendment received on 8/6/2006. Therefore, claims 14-16 and 18-28 are currently pending and are the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 7/18/2006 has been fully considered by the Examiner.

Specification

The objection to the specification regarding improper use of trademarks, as set forth on pages 3-4 of the office action mailed on 3/13/2006, is withdrawn in response to Applicant's amendments to the specification to properly identify trademarks.

Claim Objections

Claim 14 is objected to because the claim can be interpreted as reading on a mammalian subject that has exhibited increased levels of IL-17, or alternatively, a mammalian subject motivated to express an elevated level of IL-17. The Examiner suggests amending the claim to recite a mammalian subject "identified as expressing an elevated level of IL-17" or "having been determined to express an elevated level of IL-17", or something similar. It is noted, however, that these proposed amendments will not obviate the rejection under 35 U.S.C. 112, first paragraph, regarding new matter (see below).

Claim Rejections - 35 USC § 112, first paragraph – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejections withdrawn

1. Rejection of claims 14-16 and 18-28 under 35 USC § 112, first paragraph, regarding lack of enablement for interleukin (IL)-23 antagonists other than anti-IL-23 and anti-IL-23 receptor antibodies, as set forth on pages 5-6 of the prior office action mailed on 3/14/2006, is *withdrawn* in response to Applicant's amendments to the claims to recite only anti-IL-23 antibodies and anti-IL-23 receptor antibodies.

2. Rejection of claims 20-21 under 35 USC § 112, first paragraph, regarding lack of enablement for all antibody fragments, as set forth on page 6 of the prior office action mailed on 3/14/2006, is *withdrawn* in response to Applicant's arguments that the instant specification provides examples of Fv, Fab, Fab', Fa(ab')2 fragments, as well as diabodies, linear antibodies, single-chain antibodies, and multispecific antibodies formed from antibody fragments, as well as methods of making these antibodies. The Applicant argue that these teachings, coupled with general knowledge in the art at the time the instant application was filed, would allow a person of ordinary skill in the art to make and use antibody fragments in the claimed method. These arguments have been fully considered and are persuasisve.

Rejections maintained

3. Claims 14-16 and 18-28 *remain rejected* under 35 USC § 112, first paragraph, regarding lack of enablement for methods of treating all possible diseases characterized by increased IL-17, as set forth on pages 4-5 of the prior office action mailed on 3/14/2006.

In the response received on 8/9/2006, the Applicant argues that the specification teaches a correlation between the expression and biological roles of two otherwise known cytokines, IL-17 and IL-23. Specifically, the Applicants argue that the instant specification teaches that IL-23 stimulates the production of IL-17 in cell cultures, and this IL-23-mediated IL-17 production is blocked by the presence of neutralizing antibodies. The Applicant also notes that the specification teaches that IL-17 is implicated in the pathology of several inflammatory

diseases. The Applicant therefore asserts that the instant invention is enabled because the specification teaches diseases characterized by increased IL-17 levels, and a method of blocking IL-17 production.

These arguments have been fully considered and are not persuasive. It is noted that the data presented in the specification regarding the induction of IL-17 production by IL-23, as well as inhibition of IL-17 production by IL-23 neutralization, were obtained by *in vitro* experiments. It is known in the art that *in vitro* experiments do not always extrapolate to *in vivo* results. In the instant case, the Applicants are relying on *in vitro* data regarding IL-23-mediated IL-17 production, and lack of IL-17 production in IL-23p19 deficient mice. Although this does establish a biological role for IL-23 in promoting IL-17 production *in vitro*, there is no *in vivo* evidence showing that administration of an anti-IL-23 or anti-IL-23 receptor antibody would be effective in treating any disease in an intact animal. One of ordinary skill in the art would not be able to predict the efficacy of administration of the claimed method of treatment without *in vivo* experiments to show that administration of anti-IL-23 or anti-IL-23 receptor antibodies was effective and without unforeseen effects. Marshall (*Science*, 2006, Vol. 311, p. 1688-1689) teaches that in vivo administration of antibodies may have unpredictably consequences. Specifically, Marshal describes a clinical study in which patients given experimental antibodies developed severe, life-threatening reactions to the antibodies. Thus, one of ordinary skill in the art could not predict that the claimed method could effectively treat each of the recited diseases without further, undue in vivo experimentation.

Claim Rejections - 35 USC § 112, first paragraph – written description

Rejections withdrawn

1. Rejection of claims 14-16 and 18-28 under 35 USC § 112, first paragraph, regarding lack of written description for IL-23 antagonists other than anti-IL-23 antibodies or anti-IL-23 receptor antibodies, as set forth on pages 7-8 of the prior office action mailed on 3/14/2006, is *withdrawn* in response to Applicant's amendments to the claims to recite only anti-IL-23 antibodies and anti-IL-23 receptor antibodies.

Rejections necessitated by amendment

2. Claims 14-16 and 18-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claim 14 recites a method for treatment of an inflammatory disease characterized by elevated expression of IL-17, comprising administering anti-IL-23 antibodies or anti-IL-23 receptor antibodies to a mammalian subject "determined to express an elevated level of IL-17". Although the specification discloses several diseases characterized by increased IL-17 levels, the limitation "determined to express an elevated level of IL-17" can be interpreted as a method step comprising determination of IL-17 levels in a subject. After extensive review, the Examiner is unable to find, in the Specification as originally filed, support for this newly added limitation in the claim. This newly added limitation is not expressly asserted, nor does it flow naturally from the Specification as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 14-16 and 18-28 under 35 USC § 102(b) as being anticipated by Chirica *et al* (US 6,756,481), as set forth on pages 8-9 of the office action mailed on 3/14/2006, is *withdrawn*. In the response received on 8/9/2006, the Applicant argues that Chirica *et al* does not teach a method of administration of anti-IL-23 or anti-IL-23 receptor antibodies to a subject "determined to express an elevated level of IL-17". Although this limitation has been deemed to constitute new matter, as discussed supra, Chirica *et al* does not specifically teach this limitation, and therefore the rejection is withdrawn.

Conclusion

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER